Clinical Policy Title:	temsirolimus
Policy Number:	RxA.509
Drug(s) Applied:	Torisel®
Original Policy Date:	03/06/2020
Last Review Date:	10/19/2023
Line of Business Policy Applies to:	All lines of business (except Medicare)

Criteria

I. Initial Approval Criteria

A. Renal Cell Carcinoma (must meet all)**:**

1. Diagnosis of advanced RCC (i.e., relapsed, metastatic or stage IV disease);
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Prescribed as a single agent;
5. Member has at least 3 prognostic risk factors ;
6. Request meets one of the following (a or b): *
   a. Dose does not exceed 25 mg per week (50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use *(*prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

B. Endometrial Carcinoma (off-label) (must meet all)**:**

1. Diagnosis of recurrent, metastatic, and/or high-risk endometrial carcinoma;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Request meets one of the following (a or b):*
   a. Dose does not exceed 25 mg per week (50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital).
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).
   *Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

C. Soft Tissue Sarcoma (off-label) (must meet all)**:**

1. Diagnosis of perivascular epithelioid cell tumor (PEComa), recurrent angiomyolipoma, or lymphangioleiomyomatosis;
2. Prescribed by or in consultation with an oncologist;
3. Age ≥ 18 years;
4. Use is as a single agent;
5. Request meets one of the following (a or b): *
   a. Dose does not exceed 25 mg per week (50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital);
   b. Dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 6 months
Medicaid: 6 months

II. Continued Therapy Approval

A. All Indications in Section I (must meet all)**:**

1. Member is currently receiving medication that has been authorized by RxAdvance or documentation supports that member is currently receiving Torisel® for a covered indication and has received this medication for at least 30 days;
2. Member is responding positively to therapy;
3. If request is for a dose increase, request meets one of the following (a or b):*
   a. New dose does not exceed 25 mg per week (50 mg per week if member is on concomitant strong CYP3A4 inducer such as dexamethasone, phenytoin, carbamazepine, rifampin, rifabutin, rifampicin, phenobarbital);
   b. New dose is supported by practice guidelines or peer-reviewed literature for the relevant off-label use (prescriber must submit supporting evidence).

*Prescribed regimen must be FDA-approved or recommended by NCCN.

Approval duration
Commercial: 12 months
Medicaid: 12 months

References

1. National Comprehensive Cancer Network. Kidney Cancer Version 2.2022. Available at: https://www.nccn.org/professionals/physician_gls/pdf/kidney.pdf. Accessed September 9, 2022.
2. National Comprehensive Cancer Network. Soft Tissue Sarcoma Version 2.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/sarcoma.pdf. Accessed September 9, 2022.
3. National Comprehensive Cancer Network. Uterine Neoplasms Version 4.2021. Available at: https://www.nccn.org/professionals/physician_gls/pdf/uterine.pdf. Accessed September 9, 2022.

Review/Revision History	Review/Revised Date	P&T Approval Date
Policy was established	01/2020	03/06/2020
Policy was reviewed:		

1. Policy title table was updated: Line of business policy applies was updated to “All lines of business”. 2. Initial approval criteria I.B.1 updated to specify type of endometrial carcinoma. 3. Continued therapy criteria II.A.1 was rephrased to “Currently receiving medication that has been authorized by RxAdvance…”. 4. References were updated.	09/08/2020	12/07/2020
Policy was reviewed: 1. Initial and Continued Therapy Approval Criteria was updated to remove HIM approval duration. 2. Continued Therapy Criteria II.A.1 was rephrased to "Member is currently receiving medication that has been authorized by RxAdvance...". 3. References were reviewed and updated.	09/19/2021	12/07/2021
Policy was reviewed: 1. References were reviewed and updated.	09/06/2022	10/19/2022
Policy was reviewed.	10/19/2023	10/19/2023